

CONSIDERED: /G.R.W./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Meagher, Edward

Examiner: Gloria R. Weeks

Serial No.: 10/556,125

Art Unit: 3721

Filed: November 9, 2005

Conf. No: 4353

For: **ANASTOMOTIC STAPLE WITH CAPILLARY WHICH EXPELS A
BONDING AGENT UPON DEFORMATION**

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REPLY BRIEF

Sir:

This Reply Brief is in response to the Examiner's Answer mailed on January 12, 2011 to the Appeal Brief filed on November 3, 2010 for the above-identified patent application.

The **Status of Claims** begins on page 2 of this paper.

The **Grounds of Rejection to be Reviewed on Appeal** begin on page 3 of this paper.

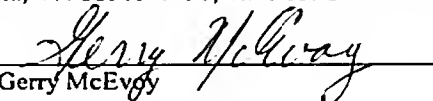
The **Arguments** begin on page 4 of this paper.

The **Appendix of Claims** begins on page 12 of this paper.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: March 10, 2011


Gerry McEvoy

I. STATUS OF CLAIMS

The status of the claims in the above-identified application is as follows:

- A) Claims 1-8 are pending; and
- B) Claims 1-8 stand rejected and are under appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant requests review of the following outstanding grounds of rejection:

A) The rejection of Claims 1-5, and 7 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,045,560 to McKean et al. (hereinafter “McKean”); and

B) The rejection of Claims 6 and 8 under 35 U.S.C. §103(a) as being unpatentable over McKean in view of U.S. Patent No. 5,263,629 to Trumbull et al. (hereinafter “Trumbull”).

III. ARGUMENT

Appellant has reviewed the Examiner's Answer and fully maintains all of his positions regarding each ground of rejection.

With regard to the rejection of Claims 1-5, and 7 under 35 U.S.C. §102(b) as being anticipated by McKean, Appellant maintains that each of Claims 1-5, and 7 are allowable over McKean. McKean fails to disclose each and every element of Appellant's invention as claimed, it fails to describe the claimed elements in the proper arrangement, and, in sum, it does not teach the identical invention. For at least these reasons McKean does not support an anticipation rejection.

According to MPEP §2131, to anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In *re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

In addition, it is "well settled that the burden of establishing a prima facie case of anticipation resides with the [United States] Patent and Trademark Office." *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1788 to 1789 (Bd. Pat. App. & Inter. 1986).

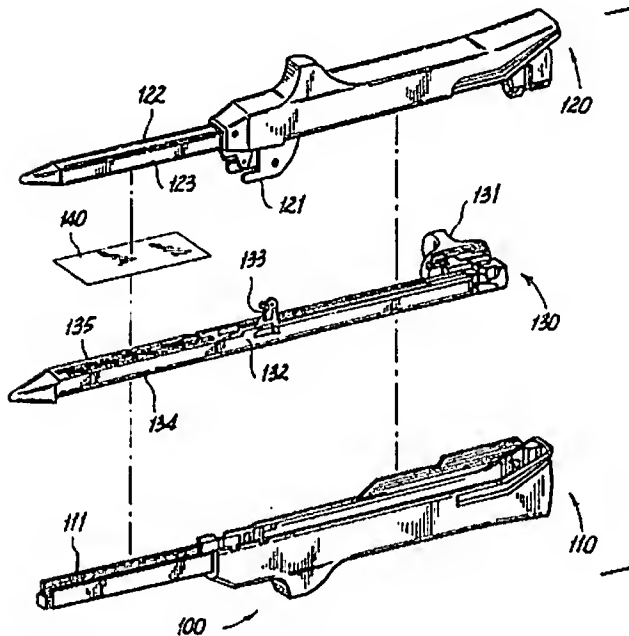
Claim 1 recites a surgical fastener for use with an anastomosis of two tissues. The surgical fastener comprises a base leg and a support leg, said base leg being selectively deformable and including at least one traumatic tip for piercing tissue, and at least one capillary

fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.

Claim 2 is directed to a surgical fastener for use with a surgical instrument for performing an anastomosis between two tissues wherein the surgical instrument includes a selectively engageable loading unit for supporting an array of surgical fasteners and an actuator for initiating deformation of the surgical fasteners, each of the surgical fasteners comprising a base leg and a support leg, said base leg being selectively deformable and including a tip for piercing tissue; and at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable to dispense said liquid upon actuation of the surgical instrument and simultaneously with the deformation of each surgical fastener.

McKean discloses a surgical stapling apparatus (100) (shown in Figs. 2 and 7 as reproduced below) having a first jaw structure (110) having a finger-like projection (111) for holding an actuating assembly 130. A disposable loading unit may include the actuating assembly. See McKean col. 3, lines 23-26. Disposable loading unit (130) is operatively associated with a cartridge assembly (135) that houses metal staples. See McKean col. 3, lines 31-32. The McKean apparatus includes a second jaw structure (120) having a finger-like projection for carrying an anvil assembly (123). See McKean col. 3, lines 26-29. Biocompatible surgical fabric (140) is disposed between the anvil assembly (123) and cartridge assembly (135). See McKean col. 3, lines 52-56. The Biocompatible surgical fabric (140) can be woven, knit, or nonwoven fabric. See McKean col. 4, lines 13-14. Biocompatible surgical fabric (140) is

releasably attached the anvil assembly (123), the cartridge assembly (135), or both the anvil assembly (123) and cartridge assembly (135). See McKean col. 4, lines 31-36. Upon actuation of the McKean instrument, staples (137) penetrate the surgical fabric (140) and tissue (150) and a tissue/fabric “sandwich” is formed. See McKean col. 4, lines 37-38 and lines 57-59.



McKean Fig. 2

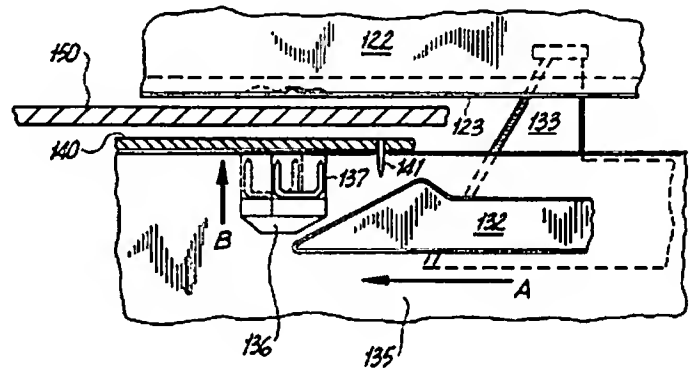


FIG. 7

McKean Fig. 7

Under MPEP §2131, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” See *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 191 3, 1920 (Fed. Cir. 1989). The prior art must describe the elements arranged as required by the claims. In *re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

The McKean reference fails to meet the burdens imposed by any of these tests.

In the Response, the Examiner contends that when the “fastener of McKean is pushed from the cartridge, the fastener will penetrate a fabric material, which is porous (thereby defining a capillary structure), such that the fabric is fixed to an external surface of the fastener.

Response, page 5, para. 1. The Examiner is incorrect. A fabric may be porous, woven, non-woven, or knit, but this does not expressly or inherently disclose a capillary structure. Nowhere does McKean teach a “capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid.” The fabric is not attached to the staple and is clearly a separate element. To reiterate, MPEP §2131 requires each and every element as set forth in the claim be found in a single prior art reference to support an obviousness rejection. Since McKean does not teach each and every element as set forth in Appellant’s claims, it cannot support an anticipation rejection.

Even assuming the Examiner were correct, which she is not, this contention would still fail because it would not describe the elements arranged as required by the claims. (In re Bond). In sum, McKean merely discloses the use of a surgical stapler with a surgical fabric buttress. The fabric placed between the staple and patient tissue so that, upon actuation of the stapler, the fabric is stapled to tissue. Appellant’s claims require a “capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid” — *not* “a staple pushed through a fabric buttress which has no capillary structure disclosed therefor” which is essentially the Examiner’s position.

The Examiner further contends that Appellant’s claim limitations are drawn to “a capillary fixed to an external surface of at least one of the base leg or support leg (the capillary) having a reservoir defined **therein**” (emphasis in original, page 5, para. 2). The Examiner conveniently omits the rest of Appellant’s limitation, which in full reads “at least one capillary

fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid" (emphasis added). As stated above, MPEP §2131 requires that in order to support an anticipation rejection the reference must show the identical invention in as complete detail as is contained in the claims, and that each and every element as set forth in the claim must be found in a single prior art reference. Since McKean fails to disclose "at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid" it cannot properly anticipate Appellant's claimed invention.

The Examiner then looks to McKean for a disclosure of a capillary containing a liquid and unsurprisingly finds none. The Examiner dismissively remarks "[w]hether the substance 'therein' is a liquid, gel or solid does not negate the structural disclosure by McKean et al. of a capillary defining a reservoir capable of containing a substance." Yet this cannot hide the fact that McKean does not and cannot offer any disclosure of "at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid".

Appellant's independent claims 1 and 2 require "said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener". Yet, on page 6, first full paragraph of the Answer, the Examiner again erroneously relies upon McKean for a "fabric/capillary" rupturable simultaneously with the deformation of [the] surgical fastener. Confoundingly, the Examiner gives a two-step example of a simultaneous event, wherein in the first step, the surgical fastener "pierces and ruptures" a "capillary/fabric" (but wherein the fastener does not deform). In the second step of the Examiner's example, the surgical fastener is deformed by the anvil, then the points of the fastener re-enter the "fabric/capillary", and,

according to the Examiner, they “rupture[e] the fabric/capillary during deformation of the surgical fastener”. Since by the Examiner’s own admission, a McKean staple is capable of rupturing the alleged capillary without deforming the staple, it differs fundamentally from Appellant’s claims which requires “at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.”

Moreover, the Examiner’s scenario would require the “fabric/capillary” to be ruptured in order for the “fabric/capillary” to be fixed to an external surface of a leg of the fastener. Yet, as claimed, Appellant’s surgical fastener includes “at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable”. Emphasis added. As used in the claim, the word “being” functions as a present participle which modifies the word “capillary” with “rupturable”. “Rupturable” is the word “rupture” combined with the suffix “-able” which, in turn, means “having the ability to be ruptured”. Appellant’s claim limitations require “at least one capillary fixed to an external surface...said at least one capillary being rupturable”. In contrast, the Examiner’s example describes a “fabric/capillary” attached to the staple *that is already ruptured*. Again, the Examiner has failed to show that the identical invention is disclosed in McKean as required by MPEP §2131.

According to MPEP §2111, the pending claims must be “given their broadest reasonable interpretation consistent with the specification.” Appellant maintains that the Examiner’s construction of the claims is not consistent with a “broadest reasonable” interpretation. However, even if the Examiner’s construction was reasonable, which it is not, it would still

require the capillary to be ruptured in order for it to be fixed to the fastener, which contradicts Appellant's claims' requirements that the capillary be both fixed and rupturable simultaneously with the deformation" and not, and the Examiner would have it, fixed and "already ruptured".

For any one or all of the reasons discussed above and in Appellant's Appeal Brief, Appellant submits that Claims 1 and 2 are not anticipated by McKean and are in condition for allowance.

Claims 2-8 and 10 depend from claim 1. For at least the reasons discussed above, *inter alia*, Appellant submits that McKean fails to anticipate claims 3-5 and 7. Accordingly, Appellant submits that claims 3-5 and 7 are also in condition for allowance and that the rejection thereof under 35 U.S.C. §102(b) be withdrawn.

**B) Claims 6 and 8 Stand Rejected Under 35 U.S.C. § 103(a)
 As Being Unpatentable Over McKean in view of Trumbull**

Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over McKean in view of U.S. Patent No. 5,263,629 to Trumbull et al. (hereinafter Trumbull). Trumbull discloses a pledget material used with a stapling apparatus. Appellant traverses this rejection for at least the following reasons.

MPEP §2143.03 states that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. Claims 6 and 8 depend from independent Claims 1 and 2 and contain all the limitations thereof. For at least the reasons presented herein, and in Appellant's Appeal Brief, Appellant maintains that because Claims 1 and 2 as currently presented are patentable, claims 6 and 8 which depend therefrom are also patentable. Accordingly, Appellant respectfully requests the rejection of claims 6 and 8 be withdrawn.

In view of the foregoing remarks and arguments, Appellant respectfully maintains that all claims now pending in this application, namely Claims 1-8, are allowable over the cited references and respectfully request allowance of these claims.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. 21-0550 therefor.

Dated: March 10, 2011

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Russell S. Salerno", is written over a horizontal line.

Russell S. Salerno
Reg. No. 53,542
Attorney for Appellant

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

Correspondence Address:
Covidien - Surgical Devices
Suite 8 N1
Legal Department
555 Long Wharf Drive
North Haven, CT 06511

IV. APPENDIX OF CLAIMS

1. (Rejected) A surgical fastener for use with an anastomosis of two tissues, comprising:

a base leg and a support leg, said base leg being selectively deformable and including at least one traumatic tip for piercing tissue; and

at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.

2. (Rejected) A surgical fastener for use with a surgical instrument for performing an anastomosis between two tissues wherein the surgical instrument includes a selectively engageable loading unit for supporting an array of surgical fasteners and an actuator for initiating deformation of the surgical fasteners, each of the surgical fasteners comprising:

a base leg and a support leg, said base leg being selectively deformable and including a tip for piercing tissue; and

at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable to dispense said liquid upon actuation of the surgical instrument and simultaneously with the deformation of each surgical fastener.

3. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said liquid in said reservoir includes at least one of a bonding agent, medicinal agent and therapeutic agent.

4. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said reservoir includes a series of chambers, each of said chambers including a liquid disposed therein selected from the group consisting of: bonding agents, medicinal agents and therapeutic agents.

5. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said liquid is a bonding agent designed to adhere to tissue upon curing.

6. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said base leg of said surgical fastener includes first and second capillaries which are designed to sequentially rupture upon deformation.

7. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said first capillary includes a medicinal agent and said second capillary is designed to include a bonding agent.

8. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said surgical fastener includes at least two capillaries which are radially disposed along the base leg of said surgical fastener.